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14. ABSTRACT

PURPOSE: To determine the effects of clinical trial (CT) characteristics on physicians' referral of minority women to breast cancer CTs. SCOPE: Activities included: a) Identifying 225 breast cancer CTs conducted in 2006 at 352 sites in California, Florida, Illinois, and New York through NCI Website; b) Interviewing 233 research team members; and c) Surveying 706 oncologists, surgeons, and radiation oncologists from the four states. FINDINGS: Almost 40% of the physicians reported discussing enrollment in a CT with their patients, while 33% said they frequently discussed the benefits/burdens of a specific CT. Oncologists were significantly more likely than other specialists to discuss enrollment and the benefits/burdens of a CT. Time spent in patient care and distance to a CT were negatively associated with referral. The most cited barriers to recruitment were study entry criteria and an indicator of patient barriers. Examination of the CT environment indicated that only one-third of the CT sites reported providing study summaries in a language other than English and less than one-half provided onsite interpreters. These results suggest that availability and accessibility play key roles in physician referral to CTs.

15. SUBJECT TERMS

Clinical trials, minorities, health care settings, communities

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The Role of the Clinical Trial Environment

Celia P. Kaplan, DrPH, MA, Principal Investigator

Final Report

INTRODUCTION

Clinical trials are the primary vehicle for transforming laboratory discoveries in breast cancer care into clinical practice. Enhanced participation by minorities in these trials is necessary to assess the effectiveness of advances in breast cancer care among major subpopulations and to ensure equity in the distribution of new treatment benefits. While inroads to increasing minority inclusion in breast cancer clinical trials have been made,[1-4] recent reports continue to demonstrate lower enrollment among African Americans, Asian Americans, and Latinos when compared to Whites.[5] Within the last decade, the average rate of increase in breast cancer incidence among Latinos and Asian Americans has risen,[6] underscoring the need for minority inclusion in cancer clinical trials. Minority participation will likely remain low without research designed to understand the reasons for limited participation and subsequent policy changes based on those findings. Therefore, to address persistent ethnic and socioeconomic disparities in cancer care, including participation in research, interventions need to assess the broader context or culture of clinical trials and include the larger community where these trials take place. Our study examined the combined effect of these factors on minority referral. To achieve this, we measured clinical trial characteristics that may impact minority recruitment, such as accessibility and availability of trials, site cultural competence, and outreach efforts. Key indicators associated with clinical trial referral were identified in order to establish the basis for a standardized methodology to assess the overall capability of clinical trial sites to include minorities.

BODY

The tasks described below represent the modified timeline and the progress made by the research team.

Task 1: Identify Breast Cancer Clinical Trials (Months 1-24). **Completed.**

Through the Physicians Data Query (PDQ®), the National Cancer Institute's comprehensive clinical trial cancer database, we identified 225 active breast cancer clinical trials and 352 clinical trial sites in California, Florida, Illinois, and New York. All identified breast cancer clinical trials and their respective clinical trial sites were entered into an Access database.

Task 2: Identify Clinical Trial Research Team Members (RTMs) (Months 12-36). **Completed.**

Using information gleaned from our online research, we identified key personnel and their contact information. Based on this information, we gathered contact information for each of the sites for a telephone interview.

Task 3: Develop RTM Survey Instruments (Months 5-9). **Completed.**

The research team used multiple modes of survey data collection including a telephone survey, a self-administered paper survey, and an online survey. The existing RTM survey instrument was reviewed and refined to meet the current study goals. Language and presentation of the instrument were amended to reflect the multimodal approach to data collection. Key informants pre-tested the survey and provided feedback.

Task 4: Conduct RTM Surveys (Months 24-48). **Completed.**

Of the initial 352 clinical trials sites selected, 85 were ineligible. Seven sites no longer conducted clinical trials, one was under new management, four did not enroll breast cancer patients, and five never participated in clinical trials. An additional 68 sites were excluded because they had the same staff and practices as another site that had already completed the survey. The remaining 267 were contacted for interviews. Twenty-two sites refused, three no longer employed RTMs and nine were never reached. This yielded 233 completed interviews for an 87% response rate.

Task 5: Identify Community Indicators (Months 12-23). **Completed.**

We have completed a review of the literature to identify appropriate census indicators. Data was collected to characterize both the physical environment and the social environment surrounding clinical trials.

Task 6: Identify Breast Cancer Physicians in California, Florida, Illinois, and New York (Months 8-24). **Completed.**

We received the AMA Physicians MasterFile and identified all physicians practicing surgery, oncology, or radiation oncology in the four selected states. Based on the data, we selected a random sample of 200 physicians of each specialty from each state (2,400 total). We also set up an internal physician Access database for tracking and follow-up.

Task 7: Develop and Refine Instrument for Physician Survey (Months 10-24). **Completed.**

The physician survey was developed and pre-tested as a paper version and an online version using DatStat Illume, a data collection software program. The paper version of the survey was professionally designed and printed.

Task 8: Recruit Physicians and Collect Data (Months 18-28). **Completed.**

Paper versions of the physician surveys were mailed to approximately 2,400 physicians. In the initial first mailing, we observed that response rates were uncharacteristically low for all four states. This was partly due

to a large number of physicians being ineligible for the study because they were either: a) no longer practicing, b) had moved out-of-state, and/or c) did not treat breast cancer patients. Another reason for the low response rate was due to a large number of addresses in the AMA Physicians MasterFile being out-of-date. Many surveys were returned due to wrong addresses or physicians who had moved and were no longer working at the address obtained from the MasterFile. Consequently, we initiated an extensive search protocol to update the address information and to verify whether they treated breast cancer patients. A total of approximately 2,100 physician addresses were searched and confirmed using the AMA physician directory and state licensing websites, followed by confirmatory phone calls. The search ensured that all physicians had updated mailing addresses and contact information. Subsequently, two additional mailings to physicians and two reminder postcard mailings were completed.

706 surveys were completed with a participation rate of approximately 46%.

Task 9: Data analysis (Months 21-48). **Completed.**

a) Descriptive analyses of the physician sample: Statistics were calculated within, and compared across gender, racial/ethnic group, geographic location and specialty. In addition, analysis focused on physician characteristics across the four states including clinical trial referral practices.
b) Analysis of clinical trial site characteristics such as accessibility/availability, cultural competence, trial benefit/burden and outreach efforts.
c) Further analysis of community indicators and refinement of population/clinical trial site maps.
d) Plotting clinical trial sites and examining the referral patterns of physicians based on distance to clinical trial sites.
e) Descriptive analyses of the research team member sample: Statistics were calculated within, and compared across state, type of research facility, and other site characteristics.

KEY RESEARCH ACCOMPLISHMENTS

- Identified 225 active breast cancer clinical trials being conducted at 352 sites across California, Illinois, Florida, and New York
- Conducted 233 surveys with RTMs at these sites (see Appendix 3 for survey)
- Conducted 706 surveys with Oncologists, Surgeons, and Radiation Oncologists who treated breast cancer patients within these states (see Appendix 3 for survey)
- Gathered data on geographic and site characteristics for clinical trial site locations
- Completed analysis of data
- Begun development of three manuscripts for publication in peer-reviewed journals

REPORTABLE OUTCOMES

- There are three manuscripts currently under development (preliminary titles):
    - Factors Affecting Referrals for Clinical Trials among Physicians from Four States
    - Geographical Distribution and Referrals for Clinical Trials among Physicians from Four States
    - The Role of the Trial Environment in Recruitment and Participation of Minorities in Clinical Trials

CONCLUSIONS

PHYSICIAN CLINICAL TRIAL PRACTICES AND BARRIERS
Below is a summary of the major findings from the physician survey (Tables 1-3).

Physician and Patient Characteristics. For the first two outcome variables, physicians were asked how often in the past year they had: a) discussed the possibility of enrolling their breast cancer patients in a clinical trial, and b) discussed the potential benefits and risks/burdens of a specific clinical trial with their breast cancer

patients. Response options were: very often, often, sometimes, rarely, or never. For analysis, responses were dichotomized into very often and often versus all other responses. For the third outcome variable, physicians were asked if, in the past year, they had referred or recruited patients to breast cancer clinical trials. Response options were yes or no.

Almost 40% of the physicians reported discussing enrollment in a clinical trial with their breast cancer patients often or very often, while 33% said they discussed the benefits and burdens of a specific clinical trial. Oncologists were significantly more likely to discuss enrollment and the benefits/burdens of a clinical trial and to actually refer or recruit their patients compared to surgeons and radiation oncologists.

Physicians who were under age 45 and who had a larger proportion of Black patients were more likely to discuss the possibility of enrollment into a clinical trial with their breast cancer patients. Surgeons or radiation oncologists and those physicians who spent more than 90% of their time in patient care were less likely to discuss enrollment.

Physicians who had a larger proportion of Black patients were more likely to discuss the potential burden and benefit of a specific trial. Surgeons, radiation oncologists, and those who spent more than 90% of their time in patient care, or had a larger proportion of Latino patients were less likely to discuss the specific burden or benefit of a breast cancer clinical trial.

Physicians who reported that at least half their patients have private insurance were more likely to refer or recruit their breast cancer patients to a clinical trial.

Practice type. Practice type was significantly associated only with referral or recruitment into clinical trials. Practices within community hospitals, teaching hospitals, and other non-NCI approved cancer programs were less likely to refer/recruit.

Distance to nearest clinical trial. Distance was negatively associated with both discussion of the potential benefits and burdens of a specific trial and with referral or recruitment to clinical trials. The further a practice was from a clinical trial site, the less likely these activities were to take place.

Physician Reported Barriers to Recruitment. Physicians were asked to indicate the degree to which 16 factors served as barriers to referring or recruiting breast cancer patients to a clinical trial. Response options ranged from 0 through 4 (0 being 'not a barrier/incentive' to 4 being 'a major barrier/incentive'. Based on maximum likelihood principal component analysis, we created four scales to assess these factors (See Table 2 for description). The remaining barrier items were analyzed individually.

'Lack of information' and 'Concern that referred patients will not return to my practice' were negatively associated with all three measured clinical trial practices. 'Eligibility or study entry criteria', the Perceived patient barriers scale, and 'Concern that trials cannot accommodate non-English speakers' were associated with increased discussion of enrollment. 'Eligibility or study entry criteria' was also associated with increased discussion of the benefits and burdens of a specific trial. And 'Eligibility or study entry criteria' and the Perceived patient barriers scale were associated with referral and recruitment into clinical trials. These positive associations with barriers suggest that the more contact a physician has with a clinical trial (e.g. actively recruits patients), the more sensitive they are to the true barriers.

CHARACTERISTICS OF RESEARCH TEAM MEMBERS AND TRIAL SITES
Below is a summary of the major findings from the RTM survey (Table 4).

Almost 40% of the RTMs we surveyed were classified as Clinical Coordinators and one-quarter of all survey participants indicated that they spoke a language other than English. Examination of the clinical trial environment indicated that half of the sites conducted at least three Phase III clinical trials. Just over half of the sites had active recruitment practices and 37% provided incentives for participation. As far as language services, 65% offered professional interpretation services for their clinical trial participants. Seventy-two percent provided consent forms in another language, 62% provided educational materials, 45% had study information, and 26% had logistical information in another language.

SUMMARY

These results suggest that availability and accessibility play key roles in discussion, referral, and recruitment in clinical trials. At this point, trial sites are underprepared for non-English speaking populations and physicians show a lack of information on specific trials. It is suggested that future work in this area be more focused on a single geographic region in order to obtain richer information on the specific local clinical trial sites and physicians. Future studies should also include a patient component, along with the physicians and researchers, in order to gain a complete picture of the factors influencing participation. The results of this study extend the current state of knowledge about factors affecting referral and participation of minorities in clinical trials and contribute to the policy implications of better geographical distribution, professional education, and accessibility to minority populations.

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Appendix 1

List of Personnel receiving pay from the research effort

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Table 1. Characteristics of Physician Respondents, by Specialty
California, Florida, Illinois and New York in 2008-2009

	Total Sample (n=706)	Surgery (n=199) 28.2%	Radiation Oncology (n=292) 41.4%	Oncology (n=215) 30.5%
Personal characteristics				
Age (mean, SD)	49.7 (8.6)	50.3 (8.9)	49.3 (8.7)	49.5 (8.3)
≤ 45	34.6	33.2	35.6	34.4
46-54	32.0	28.6	32.5	34.4
≥ 55	33.4	38.2	31.9	31.2
Women**	**25.8**	**17.6**	**27.1**	**31.6**
Race/Ethnicity**				
White	**63.5**	**70.4**	**58.0**	**64.5**
Asian	**25.8**	**17.1**	**31.3**	**26.6**
Hispanic/Latino	**7.1**	**7.0**	**6.6**	**7.9**
Black/Native American/other	**3.6**	**5.5**	**4.2**	**0.9**
State				
California	30.0	25.6	31.9	31.6
Florida	25.9	26.1	28.4	22.3
Illinois	23.5	29.2	18.5	25.1
New York	20.5	19.1	21.2	20.9
Professional characteristics				
Graduated in a foreign country	24.2	19.1	24.0	29.3
Time in patient care (mean, SD)	85.0 (15.0)	84.7 (15.5)	86.1 (13.1)	83.9 (16.8)
≤ 80%	34.3	33.8	33.8	35.5
81-90%	32.6	31.8	33.5	32.2
91-100%	33.1	34.3	32.8	32.2
Practice characteristics				
Practice Type				
Academic	11.8	78.4	73.0	73.5
Private Practice	74.7	12.6	14.0	14.0
Other (Federal, HMO, Hospital, Medical Center, Cancer Center)	13.6	9.1	13.0	12.6
Patients with private insurance (mean, SD)****	**42.0 (21.5)**	**46.4 (22.8)**	**36.7 (19.9)**	**45.3 (20.8)**
≤ 30%	**36.4**	**28.5**	**48.1**	**27.7**
31-50%	**36.2**	**35.8**	**33.5**	**40.4**
51-100%	**27.4**	**35.8**	**18.5**	**31.9**
Clinical trial practices				
Discuss the possibility of enrollment into clinical trial [a]****	**36.7**	**24.2**	**25.0**	**64.0**
Discuss the potential benefits and burdens of a specific clinical trial [a]****	**32.9**	**17.7**	**24.3**	**58.7**
Refer or recruit into clinical trials [b]*	**70.6**	**62.6**	**66.1**	**84.0**

[a] Very often/often vs. Sometimes/rarely/never, [b] Yes vs. No, *p<.05, **p<.01, ***p<.001, ****p<.0001

Table 2. Barriers to Referral and Recruitment to Clinical Trials, by Site Type
California, Florida, Illinois and New York 2008-2009 (Mean and Standard Deviation)[a]

	Total N=706	NCI-Designated CC N=55	Teaching Hospital N=75	Community Hospital N=123	Non-Accredited Hospital N=436
Eligibility of study entry criteria of trials	1.99 (1.34)	2.19 (1.35)	1.96 (1.36)	2.07 (1.30)	1.94 (1.35)
Perceived patient barriers scale[1]	1.57 (1.01)	1.27 (0.87)	1.53 (0.98)	1.58 (0.88)	1.61 (1.06)
Interaction with patients and trials scale*[2]	**1.40 (1.05)**	**1.09 (0.94)**	**1.29 (1.02)**	**1.60 (1.12)**	**1.40 (1.04)**
Lack of information*	**1.36 (1.34)**	**0.94 (1.17)**	**1.18 (1.29)**	**1.48 (1.39)**	**1.40 (1.35)**
Concern that trials cannot accommodate non-English speakers	1.04 (1.21)	1.16 (1.05)	1.17 (1.21)	1.11 (1.25)	0.98 (1.22)
Characteristics of trials scale[3]	0.96 (0.94)	0.85 (0.93)	0.77 (0.82)	1.05 (1.04)	0.98 (0.92)
Concern that referred patients will not return**	**0.82 (1.19**	**0.35 (0.82)**	**0.61 (1.04)**	**0.85 (1.21)**	**0.90 (1.24)**

[a] Based on a continuous rating scale of '0' (not a barrier) to '4' (a major barrier)
*p<.05 **p<.01
[1] Includes: 'Patient's lack of adequate insurance coverage', 'Patient's lack of understanding of what clinical trials are', 'Patient's lack of transportation', 'Patient's possible non-adherence with the study protocol', 'Patient's reluctance to complete paperwork', and 'Patient's inability to take time from work, family or other duties' (Cronbach's alpha=0.89)
[2] Includes: 'Time and effort required to explain trials to patient', 'My concern about inadequate reimbursement from research sponsors', and 'A lack of time dedicated for research' (Cronbach's alpha=0.73)
[3] Includes: 'My concern that the risks of current trials outweigh the benefits', 'My concern that trial treatment will be inferior to standard treatments', and 'Most of the trials I have seen offer little or no benefit over standard treatment' (Cronbach's alpha=0.80)

Table 3. Physician Characteristics and Clinical Trial Practices (Logistic Regression)
California, Florida, Illinois and New York in 2008-2009

	Discussed the possibility of enrolling	Discussed potential benefits and burdens of a specific trial	Referred or recruited to a clinical trial
Physician characteristics			
Age (ref = 55 or older)			
≤ 45	1.71 (1.01 – 2.91)*	1.68 (0.98 – 2.85)	0.98 (0.58 – 1.65)
46-54	0.98 (0.58 – 1.64)	0.90 (0.53 – 1.51)	1.22 (0.72 – 2.07)
Gender (ref = Male)			
Female	1.33 (0.83 – 2.12)	1.39 (0.88 – 2.21)	**1.83 (1.09 – 3.08)***
Race/Ethnicity (ref = White)			
Black/Native American /Other	0.66 (0.18 – 2.34)	**3.85 (1.26 – 11.74)***	0.92 (0.31 – 2.74)
Hispanic/Latino	0.75 (0.33 – 1.71)	1.18 (0.52 – 2.69)	1.24 (0.49 – 3.13)
Asian	**0.57 (0.34 – 0.94)***	**0.55 (0.33 – 0.92)***	0.63 (0.38 – 1.04)
State (ref = California)			
New York	0.82 (0.42 – 1.61)	0.95 (0.49 – 1.87)	0.88 (0.43 – 1.77)
Illinois	1.07 (0.55 – 2.09)	1.11 (0.57 – 2.17)	1.05 (0.51 – 2.13)
Florida	0.83 (0.41 – 1.69)	0.95 (0.46 – 1.93)	1.43 (0.69 – 2.97)
Specialty (ref = Oncology)			
Surgery	0.35 (0.20 – 0.64)***	**0.26 (0.14 – 0.47)*****	0.83 (0.43 – 1.58)
Radiation Oncology	**0.20 (0.12 – 0.34)*****	**0.24 (0.15 – 0.39)*****	0.61 (0.35 – 1.06)
Time in patient care (ref = ≤ 80%)			
81-90%	0.97 (0.58 – 1.63)	1.14 (0.68 – 1.90)	1.55 (0.88 – 2.73)
91-100%	**0.44 (0.25 – 0.77)*****	**0.40 (0.22 – 0.72)*****	0.60 (0.34 – 1.05)
Patient characteristics			
Asian patients (ref = 1st tercile)			
2nd tercile	1.01 (0.59 – 1.73)	1.09 (0.63 – 1.88)	0.91 (0.53 – 1.57)
3rd tercile	1.13 (0.60 – 2.13)	1.27 (0.67 – 2.42)	1.28 (0.66 – 2.51)
Hispanic/Latino patients (ref = 1st tercile)			
2nd tercile	0.72 (0.41 – 1.27)	0.75 (0.42 – 1.32)	1.04 (0.58 – 1.87)
3rd tercile	0.55 (0.29 – 1.02)	**0.49 (0.26 – 0.93)***	1.12 (0.60 – 2.11)
Black patients (ref = 1st tercile)			
2nd tercile	1.64 (0.97 – 2.78)	1.58 (0.93 – 2.69)	0.94 (0.55 – 1.61)
3rd tercile	**1.86 (1.03 – 3.35)***	**1.97 (1.09 – 3.56)***	0.59 (0.32 – 1.08)
Patients w/private insurance (ref = ≤ 30%)			
31-50%	1.14 (0.70 – 1.86)	0.86 (0.52 – 1.41)	0.96 (0.59 – 1.56)
≥ 50%	1.39 (0.81 – 2.40)	1.17 (0.68 – 2.03)	**2.13 (1.19 – 3.80)***
Practice type and distance to clinical trial			
Site Type (ref = NCI-designated)			
Community hospital	0.78 (0.30 – 1.99)	1.15 (0.47 – 2.81)	**0.20 (0.05 – 0.75)***
Teaching hospital	0.50 (0.19 – 1.30)	0.79 (0.32 – 1.97)	**0.22 (0.06 – 0.85)***
Not approved	0.49 (0.21 – 1.14)	0.67 (0.30 – 1.48)	**0.22 (0.06 – 0.76)***
Distance to nearest clinical trial (ref = ≤ 0.5 miles)			
0.6-5 miles	0.64 (0.39 – 1.06)	0.67 (0.41 – 1.11)	**0.45 (0.26 – 0.78)*****
≥ 5 miles	0.62 (0.37 – 1.06)	**0.48 (0.28 – 0.83)****	**0.49 (0.28 – 0.86)***
Barriers to clinical trial referral and recruitment			
Physician related barriers			
Lack of information	**0.59 (0.48 – 0.73)*****	**0.57 (0.46 – 0.70)*****	**0.71 (0.59 – 0.85)*****
Concern that patients will not return	**0.66 (0.53 – 0.81)*****	**0.72 (0.57 – 0.89)*****	**0.72 (0.59 – 0.89)*****
Patient & clinical trial barriers			
Eligibility or study entry criteria	**1.47 (1.24 – 1.75)*****	**1.31 (1.10 – 1.56)*****	**1.61 (1.34 – 1.94)*****
Perceived Patient Barriers scale	**1.37 (1.05 – 1.79)***	1.26 (0.96 – 1.66)	**1.81 (1.38 – 2.39)*****
Interaction of Patient and Trials scale	0.91 (0.72 – 1.16)	1.02 (0.80 – 1.29)	0.97 (0.75 – 1.25)
Trials cannot accommodate non-English speakers	**1.37 (1.12 – 1.68)*****	1.16 (0.95 – 1.42)	1.20 (0.95 – 1.51)
Characteristics of Trials scale	0.83 (0.64 – 1.08)	1.02 (0.79 – 1.31)	0.77 (0.59 – 1.01)

*p<0.05, ** p<0.01, *** p<0.001

Table 4. Characteristics of Research Team Members and Trial Sites California, Florida, Illinois and New York in 2008-2009		
	Total % (n=233)	
Research Team Members		
Female	92.3 (215)	
Born in U.S.	86.3 (201)	
Job Title		
Director	7.7 (18)	
Investigator	1.7 (4)	
Clinical Manager	16.7 (39)	
Nurse	23.6 (55)	
Clinical Coordinator	39.5 (92)	
Data Manager	2.6 (6)	
Administrative Personnel	7.7 (18)	
Speaks another language	25.8 (60)	
Trial Sites		
State		
California	37.3 (87)	
Illinois	19.7 (46)	
New York	20.2 (47)	
Florida	22.7 (53)	
Type of organization		
Cancer Center	40.8	
Medical groups	28.8	
Teaching Hospital	19.7	
Hospitals	10.7	
Patient Population		
% African American	12.5 (SD 16.1)	
% Latinos	15.2 (SD 18.2)	
% Asian or Asian American	6.5 (SD 11.4)	
% needs a translator	8.0 (SD 14.0)	
% patients with LEP	8.4 (SD 14.4)	
Number of Phase III clinical trials		
0-2	47.6	
3 or more	52.4	
Interpretation Services		
Professional interpretation services (on site, telephone, video)	64.8	
Professional on site interpreters	43.3	
Interpreter services by telephone	53.6	
Video interpreter services	2.6	
Materials provided	**English**	**Other languages**
Consent Forms	na	71.7
Summaries of studies	65.7	33.5
Fact sheets about studies	61.8	33.9
One or two information about studies		45.1
Directions to study site	45.1	16.7
Appointment reminder cards	69.1	17.6
One or two logistics		26.2
Study fliers or posters	59.2	29.6
Health Educational materials	85.8	56.7
One or two Educational Materials		61.8
Recruitment Practices		
Recruitment practices combined		
Ads in local paper	32.6	
Community presentations	50.2	
Any recruitment procedure	57.1	
Incentives for participation		
Travel related	33.9	
Cash or Gift cards	9.4	
Food or Beverages	14.2	
Any incentive	36.5	

The Inclusion of Minority Patients in Breast Cancer Clinical Trials

Thank you for taking time to complete this short survey about the referral of ethnic minorities into breast cancer clinical trials. Your answers will be kept completely confidential. Your individual privacy will be maintained in all published and written data resulting from the study. Your participation in the survey is voluntary.

It should take less than 10 minutes to answer all of the questions.

To learn more about this study, visit: *http://dgim.ucsf.edu/diversity/physiciansurvey.html.*

If you have any questions regarding the study or would like to speak to Dr. Celia Kaplan, please contact her by e-mail at *celia.kaplan@ucsf.edu* or by phone at (415) 502-5601.

If you do not treat patients with breast cancer, please let us know by returning this survey in the return envelope provided.

UCSF
University of California
San Francisco
Department of Medicine

Section A. Your work-related time and specialty

1. On average, what percentage of your work-related time each week do you spend in...

a.	Patient care *(e.g., seeing patients, calling consultants, reviewing lab results)*	___ %
b.	Teaching activities	___ %
c.	Research activities	___ %
d.	Administrative activities *(committee & other professionally-related activities)*	___ %
	Total should add to	**1 0 0 %**

2. What is your primary medical specialty? *Please check **one** answer only.*

- ☐ 1 Surgery
- ☐ 2 Radiation Oncology
- ☐ 3 Hematology/Oncology
- ☐ 4 Other specialty _____ *please specify*

3. Are you board-certified in your specialty?

- ☐ 1 Yes
- ☐ 0 No

4. On average, how many breast cancer patients (newly diagnosed or undergoing treatment, and including those with ductal carcinoma *in situ*) do you treat at your primary practice site per month?

_____ *breast cancer patients per month* →

If you **do not treat patients with breast cancer**, *please* **stop here** *and return the survey. Thank you.*

Section B. Characteristics of your primary practice site, patients and staff

5. Which ***one*** of the following best describes your primary practice site?

- ☐ 1 Solo practice
- ☐ 2 Single-specialty group practice
- ☐ 3 Multi-specialty group practice
- ☐ 4 Group-model HMO (e.g., Kaiser Permanente)
- ☐ 5 Public/community health center
- ☐ 6 Public hospital
- ☐ 7 VA hospital/clinic
- ☐ 8 University/medical school-based practice (not including public or VA hospitals)
- ☐ 9 Other setting _____ *please specify*

6. How many years have you practiced at your ***primary practice site***?

_____ *years*

7. In ***what year*** did you graduate from medical school?

_____

8. In ***which country*** did you graduate from medical school?
*Please check **one** answer only.*

- ☐ 1 United States
- ☐ 2 Canada
- ☐ 3 Other country _____ *please specify*

9. In ***what year*** were you born?

_____

10. Are you Latino/a or Hispanic?

- ☐ 1 Yes
- ☐ 0 No

11. What is your race/ethnicity? *Please check **one** answer only.*

- ☐ 1 Black or African American
- ☐ 2 Asian, Asian American or Pacific Islander
- ☐ 3 White, European American or Caucasian
- ☐ 4 American Indian or Alaska Native
- ☐ 5 Other _____ *please specify*

12. Using your best estimate, what percentage of your patients is insured by...

a.	Medicare (including supplemental insurance)	___ %
b.	Medicaid	___ %
c.	Private insurance or HMO (including Kaiser)	___ %
d.	No insurance/free care/self-pay	___ %
	Total should add to	**1 0 0 %**

13. Using your best estimate, what percentage of your patients is...

a.	Black or African American	___ %
b.	Asian, Asian American or Pacific Islander	___ %
c.	Latino/a or Hispanic	___ %
d.	White, European American, or Caucasian	___ %
e.	Other	___ %
	Total should add to	**1 0 0 %**

14. Using your best estimate, what percentage of your patients ***requires*** interpretation of a language other than English to receive health care services?
*Write **"0"** if all of your patients speak English.*

_____ %

15. Other than English, do you speak any of the following languages with your patients?

		Yes	No
a.	Spanish	☐ 1	☐ 0
b.	Chinese (Cantonese or Mandarin)	☐ 1	☐ 0
c.	Tagalog	☐ 1	☐ 0
d.	Vietnamese	☐ 1	☐ 0
e.	Korean	☐ 1	☐ 0
f.	Russian	☐ 1	☐ 0
g.	Other language(s) *please specify*_____	☐ 1	☐ 0

16. Do your patients speak any of the following languages as their primary language?

		Yes	No
a.	Spanish	☐ 1	☐ 0
b.	Chinese (Cantonese or Mandarin)	☐ 1	☐ 0
c.	Tagalog	☐ 1	☐ 0
d.	Vietnamese	☐ 1	☐ 0
e.	Korean	☐ 1	☐ 0
f.	Russian	☐ 1	☐ 0
g.	Other language(s) *please specify*_____	☐ 1	☐ 0

17. Are any of the following language interpreter services available at your primary practice site?

		Yes	No
a.	Interpretation by bilingual staff, including yourself *(**NOT** a professional interpreter)*	☐ 1	☐ 0
b.	Volunteer onsite interpreters *(**NOT** staff)*	☐ 1	☐ 0
c.	Professional onsite interpreters	☐ 1	☐ 0
d.	Professional interpreter services by telephone or video	☐ 1	☐ 0

18. Does your primary practice site have a bilingual (English and any other language) staff person (including yourself) in any of the following positions?

		Yes	No	No staff in this position
a.	Receptionist, front desk or appointment desk	☐ 1	☐ 0	☐ 99
b.	Nurse, nursing assistant, medical assistant	☐ 1	☐ 0	☐ 99
c.	Physician, physician's assistant or nurse practitioner	☐ 1	☐ 0	☐ 99
d.	Laboratory assistant	☐ 1	☐ 0	☐ 99
e.	Other staff _____ *please specify*	☐ 1	☐ 0	☐ 99

18a. If you answered **"Yes"** to any of the above in Question 18:
Which of the following languages does your staff person(s) speak?
*Please skip to Question 19 if you did **not** answer **"Yes"**.*

		Yes	No
a.	Spanish	☐ 1	☐ 0
b.	Chinese (Cantonese or Mandarin)	☐ 1	☐ 0
c.	Tagalog	☐ 1	☐ 0
d.	Vietnamese	☐ 1	☐ 0
e.	Korean	☐ 1	☐ 0
f.	Russian	☐ 1	☐ 0
g.	Other language(s) *please specify*_____	☐ 1	☐ 0

19. Does your office make available to your patients any educational materials about breast cancer (screening, prevention, and treatment) in any of the following languages?

		Yes	No
a.	English	☐ 1	☐ 0
b.	Spanish	☐ 1	☐ 0
c.	Chinese (Cantonese or Mandarin)	☐ 1	☐ 0
d.	Tagalog	☐ 1	☐ 0
e.	Vietnamese	☐ 1	☐ 0
f.	Korean	☐ 1	☐ 0
g.	Russian	☐ 1	☐ 0
h.	Other language(s) *please specify* _____	☐ 1	☐ 0

Section C. Your involvement in research

20. Please tell us about your interaction with university medical centers.

		Yes	No
a.	Do you have a faculty appointment at a medical school?	☐ 1	☐ 0
b.	Do you have admitting privileges at a university medical school or major teaching affiliate?	☐ 1	☐ 0
c.	In the past two years, have you consulted with a physician at a university medical center about the care of any of your patients?	☐ 1	☐ 0

21. ***In the past two years***, how many breast cancer clinical trials have you been involved in as a principal investigator or co-investigator?
*If none, please enter **"0"**.*

_____ *breast cancer clinical trials*

22. Have you ever participated ***as a patient*** in a clinical trial for any type of therapy or treatment?

☐ 1 Yes
☐ 0 No

Section D. Clinical trial referral and recruitment

23. With respect to breast cancer clinical trials, ***in the past year*** have you...

		Yes	No
a.	...had patients inquire about breast cancer clinical trials?	☐ 1	☐ 0
b.	...referred or recruited patients to breast cancer clinical trials administered by others?	☐ 1	☐ 0
c.	...recruited patients for a breast cancer clinical trial for which you were principal investigator or co-investigator?	☐ 1	☐ 0

24. ***In the past year***, have you referred or recruited patients to breast cancer clinical trials sponsored by the...

		Yes	No
a.	National Cancer Institute (NCI)	☐ 1	☐ 0
b.	NCI Clinical Trial Cooperative Groups (e.g., ECOG, NSABP)	☐ 1	☐ 0
c.	Pharmaceutical/Industry	☐ 1	☐ 0
d.	I have referred or recruited but do not know who sponsored the study	☐ 1	☐ 0

25. How often ***in the past year*** have you done the following ***with your breast cancer patients***?

		Very often	Often	Some times	Rarely	Never
a.	Discussed the possibility of enrolling them in breast cancer clinical trials	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b.	Given them informational resources (e.g., brochures, internet referrals) about breast cancer clinical trials	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c.	Discussed with them the potential benefits and risks/burdens of a specific breast cancer clinical trial	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
d.	Obtained their permission to have a staff person from a breast cancer clinical trial contact them	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

26. ***In the past year***, have you referred or recruited patients to any of the following types of breast cancer clinical trials? *Please check all that apply.*

		Yes	No
a.	Adjuvant or neoadjuvant therapy	☐ 1	☐ 0
b.	Surgical	☐ 1	☐ 0
c.	Radiation	☐ 1	☐ 0
d.	Chemotherapy	☐ 1	☐ 0
e.	Biological therapy or immunotherapy	☐ 1	☐ 0
f.	Hormonal therapy	☐ 1	☐ 0
g.	Stem cell or bone marrow	☐ 1	☐ 0
h.	Supportive care (e.g., treating clinical trial side effects)	☐ 1	☐ 0
i.	Prevention trials	☐ 1	☐ 0
j.	Other types of trials _____ *please specify*	☐ 1	☐ 0

27. Using your best estimate, how many patients have you enrolled or referred to breast cancer clinical trials ***in the past year***?
*Write **"0"** if you did not enroll or refer any patients.*

_____ *patients*

28. In your experience, who typically initiates a discussion about breast cancer clinical trials? *Please check **one** answer only.*

☐ 1 My patients initiate the discussion
☐ 2 I initiate the discussion
☐ 3 My patients and I both initiate the discussion
☐ 4 I do not discuss clinical trials with my patients

29. In general, to what degree is each of these factors a barrier for you in referring or recruiting a breast cancer patient to a clinical trial?

		not a barrier ⟷ a major barrier				
a.	Eligibility or study entry criteria of cancer clinical trials	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b.	My concern that trial treatment will be inferior to standard treatments	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c.	My concern that patients referred to trials will not return to my practice	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
d.	Time and effort required to explain trials to a patient	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
e.	My concern about inadequate reimbursement from research sponsors	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
f.	A lack of time dedicated for research	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
g.	My concern that trials cannot accommodate non-English speakers	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
h.	My concern that the risks of current trials outweigh the benefits	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
i.	Most of the trials I have seen offer little or no benefit over standard treatment	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
j.	A lack of information about trials	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
k.	Patient's lack of adequate insurance coverage	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
l.	Patient's lack of understanding of what clinical trials are	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
m.	Patient's lack of transportation	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
n.	Patient's possible non-adherence with the study protocol	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
o.	Patient's reluctance to complete paperwork	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
p.	Patient's inability to take time from work, family or other duties	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

30. In general, to what degree would the following factors serve as an incentive for you to refer or recruit a breast cancer patient to a clinical trial?

		not an incentive ⟷ a major incentive				
a.	The clinical trial is likely to improve the patient's medical condition	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b.	Patient's lack of other means to pay for health care	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c.	Patient's desire to take advantage of the latest available treatment options	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
d.	Lack of other effective treatment options	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
e.	Prevention of a recurrence or second cancer	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
f.	Patient would have access to a drug that is difficult to get authorization for outside of a clinical trial	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

You have completed our survey.
Thank you for your time and assistance!

Please return this questionnaire in the envelope provided.

UCSF
University of California
San Francisco
Department of Medicine

Clinical Trial Site #: _____

THE INCLUSION OF MINORITIES IN CLINICAL TRIALS

Thank you for taking the time to complete this short survey about the participation of ethnic minorities in breast cancer clinical trials. This survey will take approximately 5-10 minutes to complete.

Your answers will be kept completely confidential and your individual privacy will be maintained in all published and written data resulting from the study. Information that can identify you or your institution will not be shared with any third party and will be stored separately from your responses.

SECTION 1: BACKGROUND INFORMATION

1. Which *one* of the following best describes your organization? *Please mark only one.*

Solo practice	☐
Group practice (single or multi-specialty)	☐
Group-model HMO (e.g., Kaiser Permanente)	☐
Public/community health center	☐
Public hospital	☐
VA hospital or clinic	☐
University/Medical school-based practice (not including public or VA hospitals)	☐
Other practice type/ Please specify: _____	☐

2. Are you involved in clinical trials at your organization?

Yes	☐	No	☐

3. What is *your role* in your organization? *Please mark all that apply.*

a.	Principal Investigator	☐
b.	Co-Investigator	☐
c.	Clinical Research Manager	☐
d.	Clinical Trial Coordinator	☐
e.	Research Nurse	☐
f.	Data Manager	☐
g.	Administrative personnel	☐
h.	Other (please specify): _____	☐

4. Throughout your *entire* career, for how many years have you been involved in working with clinical trials? *(If less than one year, please enter "01".)* _____

5. Do you work primarily with any of the following departments? *Please mark all that apply.*

a.	General Surgery	☐
b.	Surgical Oncology	☐
c.	Medical Oncology	☐
d.	Radiation Oncology	☐
e.	Other department (please specify): _____	☐
f.	Other department (please specify): _____	☐

SECTION 2: PATIENT CHARACTERISTICS

6. Does your organization enroll breast cancer patients in clinical trials?

Yes	☐	No	☐	Don't know	☐

7. Using your *best estimate*, approximately what percentage of your breast cancer patients enrolled or recruited to clinical trials are uninsured? _____ % are uninsured

8. Thinking of race and ethnicity, what percentage of your breast cancer patients in clinical trials are …? *Please use your best estimate.*

a.	Black or African American	_____ %
b.	Latina, Latin American or Hispanic	_____ %
c.	Asian or Asian American	_____ %
	Total	100 %

9. Thinking of other characteristics, what percentage of your breast cancer patients in clinical trials …? *Please use your best estimate.*

a.	Needs a translator to receive adequate services?	_____ %
b.	Has limited ability to communicate in English?	_____ %
c.	Travel more than 30 miles to reach your center?	_____ %
	Total	100 %

SECTION 3: PATIENT LANGUAGE NEEDS AND CLINICAL TRIAL TEAM LINGUISTIC CAPACITY

10. Does any member of your breast cancer clinical trial team speak a language other than English?

Yes	☐	No	☐	Don't know	☐

11. If yes, what language(s) are spoken …? *Mark all that apply.*

a.	Spanish	☐
b.	Chinese (Mandarin or Cantonese)	☐
c.	Vietnamese	☐
d.	Another language (please specify): _____	☐
e.	Another language (please specify): _____	☐

12. Does your organization offer interpreter services to patients enrolled in clinical trials?

Yes	☐	No	☐	Don't know	☐

13. If yes, which of the following interpreter services are offered to them? *Mark all that apply.*

a.	Interpretation by bilingual staff	☐
b.	Professional onsite interpreters	☐
c.	Volunteer onsite interpreters	☐
d.	Professional interpreter services by telephone	☐
e.	Video interpreter services	☐
f.	Other/specify: _____	☐

14. Are interpreter services for clinical trial participants provided in any of the following languages? *Mark all that apply.*

a.	Spanish	☐
b.	Chinese (Cantonese and Mandarin)	☐
c.	Vietnamese	☐
d.	Another language (please specify): _____	☐
e.	Another language (please specify): _____	☐

15. Does your organization provide any of the following materials to your patients? *Mark all that apply.*

a.	Summaries of clinical trial studies	☐
b.	Frequently asked questions (FAQ) sheet about studies	☐
c.	Directions to study site(s)	☐
d.	Appointment reminder cards	☐
e.	Study fliers or posters	☐
f.	Health educational materials	☐
g.	Other printed materials: _____	☐

16. If yes, are these materials provided in a language other than English? *Mark all that apply.*

a.	Summaries of clinical trial studies	☐
b.	Frequently asked questions (FAQ) sheet about studies	☐
c.	Directions to study site(s)	☐
d.	Appointment reminder cards	☐
e.	Study fliers or posters	☐
f.	Health educational materials	☐
g.	Other printed materials: _____	☐

17. Are the following printed materials available in languages other than English? *Mark all that apply.*

a.	Consent Forms	☐
b.	Experimental Subject's Bill of Rights	☐

SECTION 4: RECRUITMENT FOR BREAST CANCER CLINICAL TRIALS

18. Please think now of your breast cancer clinical trial program's *general* recruitment practices. Which, if any, of the following approaches has been used to recruit patients to breast cancer clinical trials?

a.	Recruitment during patient clinic visits	☐
b.	Recruitment videotapes shown in waiting areas at your site	☐
c.	Advertisements in local/community newspapers	☐
d.	Discussions with potential research participants and their families by phone	☐
e.	Presentations to community, social and service groups and churches	☐
f.	Presentations to health providers to encourage referral of their patients to clinical trial studies	☐
g.	Use of research staff from targeted ethnic subgroup as recruiters	☐
h.	Participation in community health fairs or cancer awareness days	☐
i.	Others (please specify): _____	☐

19. Does your organization use any outside/third party agencies to help with recruitment efforts?

Yes	☐	No	☐	Don't know	☐

20. At your site, which of the following incentives, if any, do breast cancer clinical trials provide to clinical trial participants?

a.	Free parking	☐
b.	Parking vouchers	☐
c.	Travel allowance	☐
d.	Child care	☐
e.	Cash or gift cards/certificates	☐
f.	Complimentary food or beverages	☐
g.	Other incentive(s) (please specify): _____	☐
h.	None	☐

DEMOGRAPHIC INFORMATION

We have reached the end of the survey and I would like to finish by asking you a few questions about yourself.

1. Are you a …?

Physician	☐
Nurse	☐
Pharmacist	☐
Technician or clinical assistant	☐
Research assistant	☐
Administrative personnel	☐
Other (please specify): _____	☐

2. Are you … ?

Female	☐
Male	☐

3. Where were you born?

United States	☐
Another country (please specify): _____	☐
Decline to state	☐

4. Do you speak a language other than English?

No	☐
Yes. What language(s): _____	☐

5. How many years of education have you completed? _____

Thank you for your time and participation in this survey.